

REMARKS

CLAIM REJECTIONS - 35 U.S.C. § 102

Claims 1 and 7 are rejected under 35 U.S.C. § 102(e) as being anticipated by Paul Barstad (U.S. Pub 2002/0028476).

The Examiner states:

Paul Barstad anticipates the instant claims by teaching a method of determining thiopurine methyltransferase (TPMT) activity in a subject. This method includes the steps of reacting a sample obtained from a subject with a methylated purine product. The reacted product is then contacted with an acid and precipitated. Detecting the purine product will indicate the level of TPMT. The purine product can be detected by fluorescence (See abstract). TPMT binds to 6-methyl-mercaptopurine for purine synthesis (See Figure 1). Paul Barstad teaches that methylated purine products can be detected by a variety of quantitative techniques suitable for distinguishing them from other compounds (page 3, paragraph 0028).

PTO Paper dated 09/08/2003 at p 2.

Claim 1 has been amended to recite "assaying for the level of a TPMT-catalyzed reaction product by contacting the biological sample with an antibody that binds to a methylated reaction product of TPMT to form a complex; and detecting said complex". This is distinguishable from Barstad because Barstad neither discloses nor suggests using antibodies that bind methylated reaction products of TPMT for detection. The Examiner asserts that Paul Barstad teaches that methylated purine products can be detected by a variety of quantitative techniques suitable for distinguishing them from other compounds at page 3, paragraph 0028. However, such techniques are capillary electrophoresis, gas chromatography, gas chromatography-mass spectroscopy and thin layer chromatography. None of these methods use antibodies. Since Barstad fails to disclose this element, this publication does not anticipate.

Furthermore, Applicants respectfully submit that claim 7, a dependent claim, contains by virtue of its dependency, all the limitations of amended independent claim 1. Support for the above-identified quoted recitation is found at page 6, lines 5-12 of the specification. Applicants respectfully request this rejection be withdrawn.

Claims 1 and 7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Micheli et al. (*Clinica Chimica Acta* (1997) vol. 259, pages 161-168).

The Examiner states:

Micheli et al teaches a method that used reverse-phase high performance liquid chromatography to determine thiopurine methyltransferase enzyme activity. The method is based on the directed quantitation of 6-methyl-mercaptopurine produced from 6-mercaptopurine by crude erythrocyte lysates. The method is accurate and reliable and suitable for diagnostic use.

Id. at p.3.

Claim 1 has been amended to recite "assaying for the level of a TPMT-catalyzed reaction product by contacting the biological sample with an antibody that binds to a methylated reaction product of TPMT to form a complex; and detecting said complex". This is distinguishable from Micheli because Micheli neither discloses nor suggests using antibodies that bind methylated reaction products of TPMT for detection. Micheli merely discloses using HPLC for the determination of thiopurine methyltransferase activity (e.g., see Abstract, pg. 162, 3rd para. and pg. 4, 1st para.). Since Micheli fails to disclose this element, this reference does not anticipate.

Furthermore, Applicants respectfully submit that claim 7, a dependent claim, contains by virtue of its dependency, all the limitations of amended independent claim 1. Support for the above-quoted recitation is found at page 6, lines 5-12 of the specification. Applicants respectfully request this rejection be withdrawn.

Claims 6, 8 and 9 have been amended by changing their dependency from claim 2, which has been cancelled to claim 1. Applicants respectfully submit that these claims contain by virtue of their dependency, all the limitations of patentable independent claim 1.

CONCLUSION

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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